



REMARKS

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**I. Status of the Claims**

Prior to the instant Action, claims 110-113, 116-164, 167-172, 174-208 and 211-216 were in the case and have been examined. Presently, claims 185, 190 and 194 have been canceled without prejudice or disclaimer as being essentially redundant. Claims 110-113, 116-143, 149-152, 157-164, 167-172, 174-184, 186-189, 191-193, 195-198, 203-208, 215 and 216 have been amended without prejudice or disclaimer to even further improve their clarity. Claims 217 and 218 have been added, which are unified with the examined claims and supported by the specification.

Claims 110-113, 116-164, 167-172, 174-184, 186-189, 191-193, 195-208 and 211-218 are therefore in the case. According to the revisions to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

**II. Support for the Claims**

Support for the amended and new claims exists throughout the specification as filed and particularly in the pending claims. In light of the claims canceled to date, no fees should be due. However, any fees necessary for the introduction of the new claims should be deducted from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4200.000200.

Claims 110, 111 and 113 have been revised as suggested by the Office in a facsimile dated March 20, 2003, the only changes from the facsimile being to recite the sequences in the alternative and to use "contiguous" in the fragment claim, as supported by the pending claims.

Claim 112, 116-133 have been revised to accord with the independent claims.

Claim 134 has been revised to be the vector claim suggested by the Office in a facsimile dated March 20, 2003, and claim 135 has been revised accordingly.

Claim 136 has been revised to clarify that in the claimed fusion proteins, the fragment of claim 113 is operatively attached to a "distinct", selected nucleic acid coding region that encodes a distinct, selected peptide or protein sequence, as supported by the specification at least at page 30, line 6.

Claim 137 has been revised to recite the SEQ ID NOs of the P-TEFb kinase subunit, change "the" to "a", change "probe" to "target nucleic acid" and to add "full" before "complement". This implements the suggestions in the first series of telephone interviews with the Office.

Claims 138-143 have been revised to emphasize that the nucleic acid molecule encodes the functional P-TEFb large subunit protein as defined in claim 137.

Claim 149 has been revised to recite the SEQ ID NOs of the P-TEFb kinase subunit, which implements the suggestions in the first series of telephone interviews with the Office.

Claim 152 has been revised so that there are not two sequence variables, only one, which implements the suggestions in the first series of telephone interviews with the Office.

Claim 157 has been revised to recite "expression units" rather than "expression system" and to recite only one sequence variable at a time, which implements the suggestions in the first series of telephone interviews with the Office.

Claims 158-164, 167-172, 174-180 have been revised to accord with the independent claims.

Claim 181 has been revised to recite "expression units" rather than "expression system" and to recite only one sequence variable at a time, which implements the suggestions in the first series of telephone interviews with the Office.

Claims 182-184, 186-189, 191-193 and 195-197 have been revised to accord with the independent claims.

Claim 198 has been revised to more properly refer to claim 113. In light of the suggestions in the second series of telephone interviews with the Office, a reference to claim 111 has not been included in claim 198.

Claim 203 now separately refers to claim 111, to address the comments of the Office in the second series of telephone interviews.

Claims 204-208, 215 and 216 have been revised to accord with the independent claims.

New claim 217 has been added to reflect the alternative previously included within amended claim 152.

New claim 218 has been added to reflect the alternative previously included within amended claim 157.

It will therefore be understood that no new matter is included within the amended or new claims.

### **III. Interview Summaries and Agreement on Patentability**

Prior to the fifth Action, a number of telephone interviews were held between Applicant's representative, Shelley Fussey, and members of the Office, particularly SPE Achutamurthy, beginning on about December 05, 2002. SPE Achutamurthy advised that the former examiner had left the Office and the application had not been assigned to a new examiner. On about December 18, 2002, SPE Achutamurthy assured Applicant's representative that the new examiner would telephone Applicant's representative to discuss allowable subject matter before mailing a further communication.

The fifth Action was mailed on March 10, 2003. After receipt of the fifth Action, a number of further telephone interviews then followed with SPE Achutamurthy and Examiner Steadman between March 12, 2003 and the present date. Applicant very much appreciates the examiners' time and the guidance provided, leading to agreement.

In the first series of telephone interviews with the Office, the main interview was held on March 18, 2003. Agreement was reached regarding many issues. This was followed by a facsimile from the Office on March 20, 2003 regarding the format of independent claims that would complete agreement on allowability. On April 30, 2003 Applicant submitted a facsimile of a draft set of all claims, which adopted the Office's suggestions for allowance of March 18 and March 20, 2003, and an explanatory memo.

In the second series of telephone interviews, Examiner Steadman provided comments on the claims submitted April 30, 2003. The main interview was held on May 29, 2003. Agreement was confirmed for all central issues. Examiner Steadman's observations regarding the draft claims, as stated in the second series of telephone interviews, have been considered and further improvements are introduced via the present amendment.

The agreement reached regarding patentability is implemented by entry of the present amendment. However, Examiner Steadman indicated that as the number of claims was large, certain informalities or inconsistencies may be identified upon entry and detailed consideration of the claims. It was therefore also agreed that Examiner Steadman would telephone Applicant's representative upon consideration of the present amendment, after which any informalities or inconsistencies could be addressed by examiner's amendment if necessary to secure allowance.

The present actions are being taken without acquiescing with any of the outstanding rejections, but simply in order to progress the application to allowance as timely as possible,

particularly in light of the delays at the Office and patent term issues. As agreement was reached during the telephone interviews, Applicant presently submits a succinct response. The remarks in Applicant's earlier responses are specifically incorporated herein by reference should more details be required.

#### **IV. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

The fifth Action rejects claims 137-148, 157-164 and 167-216 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite and for failing to particularly point out and distinctly claim the invention. Although Applicant respectfully traverses, the rejection is overcome as agreed in telephone interviews documented above.

In particular, claim 137 has been revised to recite the SEQ ID NOs of the P-TEFb kinase subunit, change "the" to "a", change "probe" to "target nucleic acid" and to add "full" before "complement", implementing the agreement in the first series of telephone interviews. Claims 138-143 have been revised to emphasize that the nucleic acid molecule encodes the functional P-TEFb large subunit protein as defined in claim 137, so that it is even clearer that the recited lengths of contiguous nucleotide sequences are another feature *in addition* to the definition in the claim 137.

Claims 157 and 181 have been revised to recite "expression units" rather than "expression system" and to recite only one sequence variable at a time, which implements the agreement in the first series of telephone interviews. New claims 218 reflects the alternative to amended claim 157.

The Examiner's comment regarding claim 136 in the second series of telephone interviews has been addressed. However, rather than using "heterologous" as suggested by the Examiner, the term "distinct, selected" is used in the present amendment.

The Examiner's comment regarding the reference to claim 111 in claim 198 made in the second series of telephone interviews has also been addressed. Claim 111 has been removed from claim 198 and claim 203, which refers to claim 111, has been placed in independent form.

**V. Written Description Rejection Under 35 U.S.C. § 112, First Paragraph**

The fifth Action next rejects claims 110, 113, 116-127, 133-143, 147, 148, 157-164, 167, 168, 178-205, 208 and 211-216 under 35 U.S.C. § 112, first paragraph as allegedly lacking adequate written description support in the specification. Although Applicant respectfully traverses, the rejection is overcome as agreed in telephone interviews documented above.

The pertinent claims, *e.g.*, claims 110, 111, 113, 134 and 137, have been revised as suggested by the Office, particularly in the facsimile setting forth allowable claims dated March 20, 2003. In the second series of telephone interviews, Examiner Steadman commented that written description concerns may exist for revised claim 134 alone. However, as this claim reads exactly as suggested by a biotech practice specialist in the facsimile of allowable claims dated March 20, 2003, Applicant submits that further concerns are unwarranted.

**VI. Enablement Rejection Under 35 U.S.C. § 112, First Paragraph**

The fifth Action further rejects claims 110, 113, 116-127, 133-143, 147-155, 157-164, 167-208 and 211-216 under 35 U.S.C. § 112, first paragraph as allegedly lacking sufficient enabling support in the specification. Although Applicant respectfully traverses, the rejection is overcome as agreed in telephone interviews and facsimile of allowable claims dated March 20, 2003, as documented above.

In addition to claims 110, 111, 113, 134 and 137, which follow the Office's facsimile of March 20, 2003, claims 149, 152, 157 and 181 have been revised to implement the agreement reached in the first series of telephone interviews with the Office.

## VII. Conclusion

This is a complete response to the referenced fifth Action. In conclusion, Applicant submits that, in light of the agreement reached according to the telephone interviews and materials received from the Office, as documented herein, the present case is in condition for allowance and such favorable action is respectfully requested. Should Examiner Steadman identify any remaining informalities, a telephone call to the undersigned Applicant's representative is earnestly solicited.



Respectfully submitted,

A handwritten signature in black ink, appearing to read "Shelley P.M. Fussey".

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